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| 10/768,167 | 02/02/2004 | John Brassil | 040219.04 | 6029 |

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| EXAMINER | |
|---|---|
| SAUCIER, SANDRA E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1651 | |

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| 07/16/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/768,167 | BRASSIL ET AL. | |
| | Examiner | Art Unit | |
| | Sandra Saucier | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-16 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/9/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16, 18 are pending and are considered on the merits.

Information Disclosure Statement

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Information Disclosure Statement***

The CITATION of some of the references on PTO 1449 submitted 5/9/08 is incomplete.

MPEP37 CFR 1.98(b) requires that each publication must be identified by author (if any), title, relevant pages of the publication, date and place of publication. The date of publication supplied must include at least the month and year of publication, except that the year of publication (without the month) will be accepted if the applicant points out in the information disclosure statement that the year of publication is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the particular month of publication is not in issue. The place of publication refers to the name of the journal, magazine, or other publication in which the information being submitted was published.

37 CFR 1.98(b) requires that each reference be completely identified.

See MPEP 707.05(e) III for examples for complete citation of parts of books.

See MPEP 707.05(e)IV for examples for complete citation of electronic media such as internet citations.

## >IV. < ELECTRONIC DOCUMENTS

An electronic document is one that can be retrieved from an online source (e.g., the Internet, online database, etc.) or sources found on electronic storage media (e.g., CD-ROM, magnetic disk or tape, etc.). Many references in paper format may also be retrieved as electronic documents. Other references are retrievable only from electronic sources.

The U.S. Patent and Trademark Office follows the format recommended by World Intellectual Property Organization (WIPO) Standard ST.14, "Recommendation for the Inclusion of References Cited in Patent Documents." The format for the citation of an electronic document is as similar as possible to the format used for paper documents of the same type, but with the addition of the following information in the locations indicated, where appropriate:

(A) the type of electronic medium provided in square brackets [ ] after the title of the publication or the designation of the host document, e.g., [online], [CD-ROM], [disk], [magnetic tape];

(B) the date when the document was retrieved from the electronic media in square brackets following after the date of publication, e.g., [retrieved on March 4, 1998], [retrieved on 1998-03-04]. The four-digit year must always be given.

(C) identification of the source of the document using the words "Retrieved from" and its address where applicable. This item will precede the citation of the relevant passages.

(D) specific passages of the text could be indicated if the format of the document includes pagination or an equivalent internal referencing system, or by the first and last words of the passage cited.

Office copies of an electronic document must be retained if the same document may not be available for retrieval in the future. This is especially important for sources such as the Internet and online databases.

If an electronic document is also available in paper form it does not need to be identified as an electronic document, unless it is considered desirable or useful to do so.

**Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing elements will be the date of submission for purposes of determining compliance with the requirements based on the time**

of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

***Claim Rejections - 35 USC § 112***

INDEFINITE

Claims 1-16, 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 uses the term "exposing". This term is indefinite because it cannot be determined if contact is made between the organ the substance or if the substance merely has to be present in the room to fulfill the claim limitation.

Claims 13-15 recite that "the sensed characteristics relate to ...". It cannot be determined what degree of relationship is required because all characteristics of the organ may be said to be related to one another as the organ is an isolated, discrete functioning unit and is being maintained in a metabolically active state.

The "sensing" is performed by a sensor, which is interpreted to be a type of transducer, in claim set 1-15, while in claim set 16 and18 a sensor is not required, but the claims merely require that a sensing takes place. Sensing may be done by a human in a non-empirical manner. Thus, the claims appear to be open to a visual monitoring or a more or less vague perception or impression of the operator or on the bench chemical procedure monitored by the operator which may be interpreted as "sensing". Thus, it is uncertain what the metes and bounds of the claimed method are and if they are fully supported over their entire scope by the disclosure of the specification.

***Response to Arguments***

Applicants argue that all is explained in the specification, but without explaining the metes and bounds of the terms which can have different plain

meanings. Thus, the arguments are unpersuasive of error in the rejection.

***Claim Rejections - 35 USC § 103***

Claims 1-16, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/06292 [IDS] in combination with WO 96/298865 [IDS] and Wiley *et al.* [U] or Nakahara *et al.* [V] and The Handbook of Human Tissue Sources [U1] in light of the statement of the National Center of Research Resources [V1].

The claims are directed to a method of testing substances on an organ comprising: analyzing whether the organ is suitable for transplantation and if not suitable, perfusing the organ with a first medical fluid, "exposing" the organ to a test substance, gathering data. Dependent claims require the use of two medical fluids and the testing of an immunotoxin.

WO 94/06292 discloses a method of organ perfusion where physiological or pharmacological research, i.e. effects of compounds, may be performed on the organ. Upstream sensors and downstream sensors monitor the perfusate for characteristics of pH, electrolytes and other characteristics. The sensors generate signals and are transmitted in real time, stored for future analysis or both (page 12). Duplicate organs may be perfused with perfusate that differs in only one component (pages 15 and 17). The effect of the component may be measured by the characteristics of the perfusate or other means.

WO 96/298865 teach the use of two perfusates in a method of organ perfusion. The first is a crystalloid solution and the second is a blood based solution (pages 26, 27). Thus, it is known to perfuse an organ with a first fluid to remove residual blood and other fluids and then with a second fluid which is a blood based fluid. Also, pharmaceutical and physiological agents may be perfused (page 6).

Wiley *et al.* teach perfusion of an organ with two immunotoxins in a transplantation model.

Nakahara *et al.* suggest that immunotoxins might be useful for pretreatment of organ allografts.

The perfusion of an organ with an immunotoxin in the method of WO 94/06292 which teach the testing of compounds in an *ex vivo* organ perfusion method would have been obvious because such immunotoxins may be valuable in organ transplantation methods as described by Wiley *et al.* or Nakahara *et al.* and thus may be tested in the method described in WO 94/06292 which invites the use of any test compound without restriction.

Further, the method of WO 94/06292 may be modified by the use of two distinct medical fluids as described in WO 96/298865 in the absence of evidence of criticality.

The Handbook of Human Tissue Sources states that the Human Tissues and Organs for Research unit focuses on the retrieval and distribution of tissue and organs. The website of the Human Tissue and Organ Resource for Research from the National Institutes of Health, states that the unit provides an opportunity for people who wish to become donors, but whose tissues and organs cannot qualify for transplantation and might otherwise be discarded to donate their tissues and organs for research.

Since WO 94/06292 is silent with regard to the suitability or unsuitability for transplantation of the organ to be tested in the described pharmacological method, it can be considered to be open to the use of both these subsets of organs.

The use of an organ which is not suitable for transplantation in a method of research such as the testing compounds in physiological or pharmaceutical research as taught by WO 94/06292 is well within the purview of one of skill in the art and it is known that banks have been made available to researchers for the express purpose of donating organs unsuitable for transplantation for use

in research.

One of skill in the art may use an organ which has been determined to be unsuitable for transplantation in the absence of evidence to the contrary especially because such banks and exchange resources have been instituted for research on such unsuitable organs.

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground of rejection.

WO 98/09166 discloses a method for perfusing an organ with an emulsion blood substitute, administering test compounds, analyzing the perfusate for the concentration of the test compounds, thereby determining the ability of the compound to effect absorption, distribution, metabolism, excretion and pharmokinetics of the drug. It is not cited against the claims at this time, but is of interest.

***Conclusion***

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the

advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). It is applicants' burden to indicate how amendments are supported by the ORIGINAL disclosure. Please note that a response which does not specifically point out the support for amendments to the claims may be considered nonresponsive, see MPEP 714.02.***

Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information

for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sandra Saucier/
Primary Examiner
Art Unit 1651